

REMARKS

General

Claims 49-52, 55, 71-73, 76, 80, 84, 166-172, 176-181, and 217-220 are pending in the present application. In this response, claims 49, 76, 80, and 84 have been amended and new dependent claims 219 and 220 have been added.

Exemplary support for the claim amendments and new dependent claims can be found throughout the application as originally filed. See, for example, page 66, lines 1-13 and page 67, lines 1-20 of the present specification.

Applicants would like to thank the Examiner for granting an Interview on June 4, 2009. Applicants would also like to thank the Examiner for indicating that the outstanding rejections will be overcome if the size of the gold particles recited in the present claims is amended to recite about 20 nm to about 140 nm. As discussed with the Examiner, independent claim 49 has been amended to recite gold particles having a diameter of from about 20 nm to about 140 nm.

Applicants respectfully request the Examiner to reconsider and withdraw the outstanding rejections in view of the foregoing amendments and the following remarks.

Rejections under 35 U.S.C. § 103

(i) Claims 49-52, 55, 76, 166-172, 176-179, 217, and 218 have been rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over U.S. Patent No. 4,647,544 (hereinafter "Nicolì") in view of Roth, "*The preparation of protein A-gold complexes with 3 nm and 15 nm gold particles and their use in labelling multiple antigens on*

ultra-thin sections", Histochemical Journal 14, 791-801 (1982) (hereinafter "Roth").

This rejection is respectfully traversed in light of the foregoing claim amendments.

Legal Standard

The Office has the initial burden of establishing a factual basis to support the legal conclusion of obviousness. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). For rejections under 35 U.S.C. § 103(a) based upon a combination of prior art elements, in KSR Int'l v. Teleflex Inc., 127 S.Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (2007), the Supreme Court stated that a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. In re Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).

Present Claims

Amended independent claim 49 is the only independent claim pending in the present application. Claims 50-52, 55, 76, 166-172, 176-179, 217, and 218 depend from claim 49. Claim 49 recites a population of scattered light-detectable gold particles. The gold particles of claim 49 have a diameter of from about 20 nm to about 140 nm and have less than a 5% coefficient of variation in size. The population of gold particles in claim 49 excludes polystyrene particles.

Cited Art

The Examiner's position is that Nicoli discusses "colloidal gold particles which have been coated with a variety of macromolecules such as avidin, lectins, IgG in

the size range of 20 to 500 nm (column 15, lines 25-35)." (Office Action, Page 2).

The Examiner concedes that Nicoli fails "to teach that the coefficient of variation in size of the population of particles is less than 5%". (Office Action, Page 3).

Accordingly, the Examiner cites Roth as allegedly directed to "a population of monodisperse 15 nm gold particles". (Office Action, Page 3).

Differences between Cited Art and Present Claims

As conceded by the Examiner, Nicoli does not disclose or suggest gold particles having less than a 5% coefficient variation in size. Roth does not specifically disclose less than a 5% coefficient variation in size. Moreover, even if the gold particles in Roth have less than a 5% coefficient variation in size, Roth does not disclose or suggest gold particles having a diameter of from about 20 nm to about 140 nm.

Accordingly, Nicoli and Roth fail to disclose or suggest gold particles having a diameter of from about 20 nm to about 140 nm and having less than a 5% coefficient variation in size, as presently recited in claim 49.

In view of at least the foregoing, Nicoli and Roth fail to disclose or suggest all the features recited in claim 49. Accordingly, a prima facie case of obviousness of claim 49 has not been established. As claims 50-52, 55, 76, 166-172, 176-179, 217, and 218 depend either directly or indirectly from claim 49, a prima facie case of obviousness of 50-52, 55, 76, 166-172, 176-179, 217, and 218 has not been established for at least the same reasons discussed hereinabove.

Secondary Considerations

Further, even if it were assumed arguendo that a prima facie case of obviousness has been established, secondary considerations, such as, unexpected

results can overcome the prima facie case of obviousness. In this regard, Nicoli discusses carrier particles consisting of polystyrene latex, which are used to perform the assay in conjunction with gold particles. (Col. 15, lines 28-33). The present specification describes that when using gold particles only, the particle sizes of the gold particles can be differentiated with certainty. The present specification further provides that the use of polystyrene particles in conjunction with gold particles is not desirable because it is not possible to differentiate with certainty the particle sizes of both the gold particles and the polystyrene particles. (See, for example, page 66, lines 7-13 and page 67, lines 1-20). Thus, it has been unexpectedly found in the presently pending application that using gold particles and not a combination of gold particles and polystyrene particles, unexpectedly results in greater certainty in differentiating particle sizes. This is desirable because greater certainty in differentiating particle sizes allows for improved assays. (See, for example, page 62, lines 20-33 and page 63, lines 1-15 of the present specification).

Further, the presently recited scattered light-detectable gold particles having a diameter of from about 20 nm to about 140 nm have unexpectedly desirable light scattering power compared to other materials such as polystyrene. (See, for example, pages 61-69 of the present specification). Moreover, the present specification shows that the relative scattering power of the presently recited gold particles unexpectedly increases exponentially from a diameter of about 20 nm to about 140 nm. (See, for example, Table 5 at page 66 of the present specification).

Thus, Nicoli and Roth not only fail to disclose or suggest gold particles having a diameter of from about 20 nm to about 140 nm and having less than a 5% coefficient variation in size, as discussed hereinabove, Nicoli and Roth also fail to

show the above-discussed unexpected advantages of the presently recited population of gold particles which excludes polystyrene particles.

In view of at least the foregoing, the obviousness rejection over Nicoli and Roth should be withdrawn.

(ii) Claims 71 and 72 have been rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Nicoli in view of Roth and further in view of U.S. Patent No. 4,929,400 (hereinafter "Rembaum"). Claim 73, 80, and 84 have been rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Nicoli in view of Roth and in view of Rembaum, and further in view of U.S. Patent No. 5,552,086 (hereinafter "Siiman"). Claims 180 and 181 have been rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Nicoli in view of Roth and further in view of U.S. Patent No. 5,567,628 (hereinafter "Tarcha"). These rejections are respectfully traversed.

The discussion hereinabove regarding Nicoli and Roth is herein incorporated in its entirety. Claims 71-73, 80, 84, 180, and 181 depend from claim 49. Rembaum, Siiman, and Tarcha have been cited to allegedly teach the features recited in dependent claims 71-73, 80, 84, 180, and 181 as listed hereinabove. Rembaum, Siiman, and Tarcha fail to cure the above-noted deficiencies of Nicoli and Roth. In view of at least the foregoing, the cited references fail to disclose or suggest the features recited in claim 49. Accordingly, the rejection of the claims dependent from claim 49 should be withdrawn for at least the same reasons.

New Claims

Dependent claims 219 and 220 have been added to the listing of the claims. Claims 219 and 220, which depend from claim 49, are patentable over the cited references for at least the reasons discussed hereinabove.

Conclusion

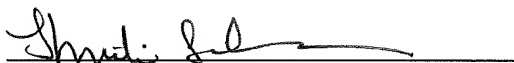
Applicants invite the Examiner to contact Applicants' representative at the telephone number listed below if any issues remain in this matter, or if a discussion regarding any portion of the application is desired by the Examiner.

In the event that this paper is not timely filed within the currently set shortened statutory period, Applicants respectfully petition for an appropriate extension of time. The fees for such extension of time may be charged to our Deposit Account No. 02-4800.

In the event that any additional fees are due with this paper, please charge our Deposit Account No. 02-4800.

Respectfully submitted,

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By: 
Shruti S. Costales
Registration No. 56,333

Customer No. 21839
P.O. Box 1404
Alexandria, VA 22313-1404
(703) 836-6620